



AN INDECIPHERABLE DEBATE? AN OVERVIEW OF OPPOSING PERSPECTIVES AND THE SEARCH FOR A COHERENT REGULATORY SCHEME FOR THE REPROCESSING AND REUSE OF SINGLE-USE MEDICAL DEVICES

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**An Indecipherable Debate?
An Overview of Opposing Perspectives and
the Search for a Coherent Regulatory Scheme for
the Reprocessing and Reuse of Single-Use Medical Devices**

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Introduction.

Johnny Baird, a 74-year-old-retiree from Arlington, Texas, had his right cornea accidentally burned during a 1993 ostensibly-routine cataract surgery at Arlington Memorial Hospital. Today, Baird is nearly blind in his affected eye, and is also in such pain that he plans to have the eye replaced with a glass one. In the course of investigating the cause of his mishap, Baird discovered a hospital incident report, which stated that a disposable laser tip was utilized in his care. However, one notable detail evident in the hospital's report indicated that the so-called "disposable" laser tip had *not* been disposed of after its initial use, but was instead resterilized and reused in Baird's surgery. Baird's malpractice suit, which he won in district court and lost on appeal, is now pending before the Texas Supreme Court.¹

Recently, unfortunate tales like Baird's have appeared in the press with increasing frequency and urgency. One familiar story involves a piece of metal that broke off a catheter and lodged inside the heart of a 32-year-old Kansas woman early in 1999. The catheter was also labeled disposable; but instead, it was resterilized and reused six times.² Reports have also emerged in the media of two patients blinded in one eye; a premature baby whose foot was burned; and increased rates of pneumonia in children.³ And even further: accounts of

¹Dana Hawkins, "Hospitals' reused tools: reassessing the risk to you," *U.S. News & World Report* (November 29, 1999) at 74.

²"FDA exposes patients to risks of medical recycling," *USA Today* (November 30, 1999) at 18A.

³"Testimony, February 10, 2000, Robert O'Holla, Vice President of Regulatory Affairs, Johnson & Johnson, House Commerce Oversight and Investigations, Reuse of Medical De-

a needle tip that broke off in a patient's jawbone; a guidewire tip that snapped off in a patient's throat;⁴ and five infants who developed lung infections linked to the reuse of syringes.⁵

"Blood money." "Dirty medicine." "Risky recycling." These are just a few of the phrases that the media has used to describe a common occurrence in many hospitals today: the reuse of medical instruments that have been labeled "for single-use only."⁶ Reading these chronicles in the press, one may wonder why such a seemingly perilous practice continues or has not yet been banned by appropriate legislation. In truth, however, there are many complex and conflicting sides to this issue, which has spawned a vigorous debate that currently involves the highest branches of the federal government, the Food and Drug Administration (FDA), hospitals and other health care providers, medical device manufacturers, and concerned consumer and physicians' groups all around the nation.

In the interests of curbing health care costs and reducing medical waste, many clinics and hospitals routinely recycle everything from surgical clamps and forceps to biopsy needles and the tiny angioplasty balloons inserted in heart patients' arteries to clean out potentially life-threatening blockages. Some commentators estimate that this practice has been going on for over two decades.⁷

Furthermore, in defense of reuse, health care administrators claim that in this vices," *Federal Document Clearing House Congressional Testimony* (February 10, 2000) [hereinafter O'Holla statement].

⁴ *Id.*

⁵ "Hospitals reuse medical devices designed for one-time use only," *USA Today* (November 29, 1999) at 28A.

⁶ John Berlau, "A Ticking Medical Time Bomb?," *Investor's Business Daily* (September 15, 1999) at A1.

⁷ *Id.*

age of skyrocketing health care expenditures, disposing of certain medical instruments after only one use simply does not make any sense.

Caught in the middle of this controversy, the FDA has struggled for only the past few years to devise a conclusive regulatory strategy for medical device reuse. Many critics claim, however, that this action by the FDA comes too little and too late. Indeed, one angry journalist has said of the FDA: “Acting more like a lookout than a law enforcer, the Food and Drug Administration has spent the past 22 years standing aside as hundreds — perhaps thousands — of hospitals have begun reusing disposable medical devices, even though such devices have been bathed in blood, and even though the instruments carry warnings against the practice.”⁸ Not wishing to rush to judgment like these and other impassioned consumer groups, though, the FDA has chosen to proceed cautiously thus far, seeking first to discern and articulate the many discordant views in this debate before formulating a final guidance rule.

This paper will explore, in turn, the many different perspectives inherent in the dispute over medical device reuse: the patient and consumer perspective; the health care provider perspective; the device manufacturer perspective; and also, the perspective of a new industry player, the third-party medical device reprocessor. It will then proceed to review the brief history of FDA regulation of medical device reuse from its outset to the current day. Finally, it will conclude with recommendations for additional measures the FDA ought to consider in arriving at an ultimate regulatory scheme.

⁸“FDA exposes patients to risks of medical recycling,” *supra* note 2.

Background.

The practice of reusing medical devices labeled, or otherwise intended, for only one use (hereinafter referred to as “single-use devices” or SUDs) apparently began in hospitals in the late 1970s.⁹ Prior to this time, most medical devices were considered to be “reusable” (that is, equipment that could be used and reprocessed multiple times). Because most reusable devices were fabricated from glass, rubber, or metal, early reprocessing of reusable products such as probes and surgical instruments involved little more than handwiping, dipping, and soaking in disinfection solutions such as hydrogen peroxide or peracetic acid.¹⁰ In the 1970’s, Original Equipment Manufacturers (OEMs) began to sell “single-use” medical devices, as a result of market demand for disposable equipment, the development of new plastics, and the application of new sterilizing agents such as ethylene oxide.¹¹ Subsequently, hospitals began to see in the medical device market products labeled “single-use only” that appeared, in structure and function, very similar to devices that had formerly been distributed or continued to be distributed as “reusable.” It is believed that the practice of reprocessing single-use devices expanded when an increasing number of hospitals decided that reuse was a cost-saving measure, and when the amount of medical waste generated by the use of disposable devices became noticeable.¹²

The decision to reuse SUDs further led hospitals to begin reprocessing more and

⁹Center for Devices and Radiological Health (CDRH), “FDA’s Proposed Strategy on Reuse of Single-Use Devices,” <<http://www.fda.gov/cdrh/reuse/singleuse.html>>.

¹⁰*Id.*

¹¹*Id.*

¹²*Id.*

more complex products (for example, balloon angioplasty catheters and cardiac catheters), products that required more involved decontamination sterilization procedures. These procedures might involve wiping the particular device of visible soil at the point of use, or containing and transporting the device to a separate decontamination or sterilization work area. As a result, an industry of third-party reprocessors emerged and evolved in response to the reprocessing needs of hospitals.

The expansion of this industry of third-party reprocessors, as well as the types of single-use products that have thus far been subject to reprocessing, has greatly intensified public concern regarding patient safety, informed consent, and the ethics of this practice. In addition, many groups have found the issue of equitable regulation of OEMs and reprocessing firms to be a particularly troubling one. An OEM may label a medical device for either multiple use (e.g., an x-ray machine, a ventilator, or an infusion pump) or for single use (e.g., an implantable device, an endotracheal tube, or examination gloves). Remarketing industries now exist for both of these types of devices. These remarketing activities may consist of reprocessing, refurbishing, rebuilding, servicing, reconditioning, cosmetically enhancing, or marketing a device “as is” for reuse. In some cases, such remarketing activities may have the potential to significantly change a finished device’s performance, safety specifications, or intended use. Therefore, many affected consumers have called for FDA to regulate reprocessing firms as strictly and in the same manner as OEMs.

Statistics

According to certain studies, about 1 million disposable devices are reprocessed every year in the United States.¹³ At least one in three hospitals nationwide reuses some devices.¹⁴ And another survey of 1238 Canadian hospitals and limited surveys in Britain and the United States have suggested that some forty percent of institutions reuse medical devices intended for single use.¹⁵ The practice has spawned a \$20 million reprocessing industry of loosely-regulated companies that clean and sterilize equipment for medical facilities.¹⁶

The FDA revealed, in an April issue of the Biomedical Market Newsletter, that 464 adverse incidents in the last half of 1999 could possibly have been attributed to the controversial practice of the reuse of single-use medical devices. The 464 incidents, out of approximately 300,000 reported between August 19 and December 7, 1999, included roughly 70 different product types.¹⁷

However, Dr. David Feigal, Director of the FDA Center for Devices & Radiological Health (CDRH), has stated that FDA “can discern no pattern of failures with reused SUDs that differs from patterns observed with the initial use of SUDs.”¹⁸ And according to FDA spokeswoman Sharon Snider, “we have no

¹³Sylvia Pagan Westphal, “Medical Reuse Rules Proposed: FDA Announces Measures for Stricter Control on Reprocessing Disposable Hospital Devices,” *Los Angeles Times* (November 2, 1999) at A3.

¹⁴Timothy B. Wheeler, “Hospital recycling coming under fire; Patients should know of reuse, senator says,” *The Baltimore Sun* (February 11, 2000) at Business 1C. *See also* “Testimony, February 10, 2000, Philip Grossman, House Commerce Oversight and Investigations, Reuse of Medical Devices,” *Federal Document Clearing House Congressional Testimony* (February 10, 2000) [hereinafter Grossman statement].

¹⁵“Reuse of Single-Use Equipment,” 268 *Lancet* 1342 (1985) (Letter to Editor).

¹⁶*Id.*

¹⁷“FDA Reveals Over 400 Adverse Incidents Involving Reuse of Medical Devices,” *Business Wire* (April 3, 2000), Healthwire Section. *See also* “Testimony, February 10, 2000, David W. Feigal, Director, Center for Devices and Radiological Health, House Commerce Oversight and Investigations, Reuse of Medical Devices,” *Federal Document Clearing House Congressional Testimony* (February 10, 2000) [hereinafter Feigal statement].

¹⁸“FDA Reveals Over 400 Adverse Incidents Involving Reuse of Medical Devices,” *supra* note 17.

data to indicate people are being injured” by the practice. Says Snider, only 245 of the 300,000 reports of serious device malfunctions received by the agency in the last total three years could be tied to the reuse of disposable equipment.¹⁹

These ambiguous statistical findings have provided fuel for the arguments of both sides of the continuing discussion: should hospitals and other health care providers be allowed to reuse SUDs or not? Let us now examine the perspective of each stakeholder in this debate for diverging opinions on the subject.

The Patient Perspective: The Dangers of Reprocessing and Reuse.

In the view of patients and other health care consumers, the reprocessing of single-use medical devices presents a number of potentially significant health risks. For the following and other reasons, several foreign health authorities have banned or disapproved all forms of disposable device reprocessing entirely.²⁰ FDA and Congress are currently debating whether or not they and the U.S. should follow suit; and patient and consumer groups strongly believe that they should.

One possible health risk, according to consumers, is that the physical act of disassembling, cleaning, and manipulating the device during reprocessing may

¹⁹Wheeler, *supra* note 14,

²⁰*See, e.g.,* Commonwealth of Australia, Dep’t of Human Services & Health, *Draft Statement of Commonwealth Policy on the Reuse of Single-Use Therapeutic Devices* (May 30, 1994). In addition, several European countries, including Italy and Spain, have prohibited reuse of single-use devices, and a number of other countries, including England and France, have issued statements disapproving reuse of disposable products. *See* Canadian Hospital Association, *Report on the Reuse of Single-Use Medical Devices* tbl.3 (1995) (discussing international perspectives).

adversely affect the device's safety or effectiveness. Also, inappropriate sterilization methods may damage device components or materials. For example, certain devices that incorporate flexible plastics may crack or otherwise be damaged under the heat and pressure of steam sterilization.²¹ Similarly, chemical germicides used in cleaning may cause surface cracking or "pitting," which may decrease the mechanical integrity of a device and make it more difficult to contaminate and clean before a later use.²² Illustrating these principles, in one particular case of reprocessed hemodialyzers, for example, the use of overdiluted chemical sterilization agents has been blamed for outbreaks of bacterial and viral infections.²³

Conversely, excessively concentrated cleaning agents and inadequate flushing also may have serious health effects. For example, some reprocessors use formaldehyde, a known carcinogen, for disinfection. Formaldehyde residues may remain in the reprocessed device, which may be infused into patients' bloodstreams.²⁴ Moreover, to ensure the safety and effectiveness of reprocessed devices, it is also vitally important, in patients' view, to determine the maximum number of reprocessing cycles. For this purpose, devices designed specifically for reuse

²¹ "ENT Endoscopic Sheath Barrier Claims Should Be Based on 30nm or Smaller Virus Size, FDA Says," *F-D-C- Rep.* ("The Gray Sheet"), Nov. 11, 1996, at I&W6.

²² Food and Drug Administration (FDA), "Guidance on the Content and Format of Pre-market Notification [510(k)] Submissions for Liquid Chemical Germicides" (Apr. 26, 1995) at <<http://www.fda.gov/cdrh/ode/germic4.html>>.

²³ An outbreak caused the deaths of fifteen patients treated at one dialysis center. See Janice M. Hogan and Thomas E. Colonna, "Products Liability Implications of Reprocessing and Reuse of Single-Use Medical Devices," 53 *Food and Drug Law Journal* 387 (1998). Insufficient disinfection of reprocessed hemodialysis equipment also has been linked to transmission of the HIV virus in several foreign countries. See, e.g., "HIV Transmission in a Dialysis Center — Colombia (1991-1993)," 274 *JAMA* 372 (1995); and M. Velandia Scott et al., "Transmission of HIV in Dialysis Centre," 345 *Lancet* 1417 (1995).

²⁴ In addition, reprocessing workers may experience serious adverse effects from exposure to formaldehyde vapors where environmental conditions are inadequately controlled. See Hogan & Colonna, *supra* note 23, at 387.

incorporate mechanisms that signal to reprocessors the point at which devices should be discarded due to deterioration, rather than reprocessed for further reuse.²⁵ However, medical devices intended for single use incorporate no such signaling mechanisms.²⁶ Therefore, patients and other consumer groups argue that reprocessors have no guidance regarding how many additional times a labeled “single-use” device may be reused.

FDA’s own research has uncovered problems with some reused disposable devices, such as angioplasty balloons that get stretched out of shape through the cleaning.²⁷ And many concerned consumers believe that the practice of reuse is entirely too common and overlooked at many hospitals and clinics. As one reader of *The New York Times* noted in a letter to the editor:

The reuse of medical devices is of great concern to kidney dialysis patients, who often have no choice but to accept what is offered or not receive this lifesaving treatment. Should an accident occur in a dialysis unit and a patient becomes very sick or even dies, the first procedure is to stop reuse of the dialysis filters until the problem is investigated. This offers a clue about the dangers of reuse.²⁸

Joel Schoenfeld, CEO of UNIVAC Inc., a maker of auto-disposable syringes, has also asserted that only syringes that cannot be reused should be available.

“The United States must declare war — war against disease,” he said.²⁹ A

²⁵See FDA, “Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: Draft Reviewer Guidance” (April 1996).

²⁶FDA has noted the impact of device design on successful reuse and reprocessing. For example, the agency has stated that, “[a]s a rule, a reusable device should be designed so that it can be adequately cleaned. If a device cannot be adequately cleaned, any subsequent disinfection or sterilization process may not achieve the desired result.” *Id.*

²⁷“Hospital Recycling Scrutinized,” *Dayton Daily News* (February 11, 2000) at 15A.

²⁸Gerald H. Dessner, “Single Use Medical Devices Are Often Used Several Times,” *The New York Times* (November 13, 1999) at A14.

²⁹Cheryl A. McMullen, “FDA studies instrument reuse,” *Waste News* (February 21, 2000) at 3.

vaccine administered in a reused syringe does more harm than good, according to Schoenfeld.³⁰

Recent Attempts at Patient Legislation

One powerful Maryland state senator believes that recycling SUDs may be too risky for the operating room. Senator Thomas L. Bromwell, a Baltimore County democrat and chairman of the Maryland state Finance Committee, has taken aim at this practice by introducing a bill this past February that would forbid hospitals and clinics in Maryland from reusing single-use devices unless they first notify patients and get their signed consent. Failure to do so could yield a fine of up to \$10,000 per violation.³¹ “These devices are labeled for one-time use only for a very good reason,” Bromwell said in a statement prepared for a February hearing on the bill in Annapolis. “That reason is that there is no scientific proof they can be sterilized and reused safely.”³²

In California, Assemblyman Thomas Calderon (D-Montebello) also announced, in August 1999, the introduction of a bill to ban, for a proposed period of two years, the use of reprocessed devices in the state.³³ And U.S. Senator Richard Durbin (D-Illinois) has also begun to instigate FDA action at the federal level, recently pushing through an amendment to an appropriations bill that will provide \$1 million for the FDA to begin providing more oversight of the reuse of

³⁰ *Id.*

³¹ Wheeler, *supra* note 14.

³² *Id.*

³³ Westphal, *supra* note 13.

single-use medical devices.³⁴ According to his spokeswoman Melissa Merz, FDA needs to ensure “that reprocessed devices be as safe as new devices.... The fact remains that Congress needs to go further to ensure patients are informed before a recycled device is used on them.”³⁵

Most recently, Representative Anna G. Eshoo (D-California) and Representative Fred Upton (R-Michigan) introduced legislation that would limit the practice of reprocessing and reusing medical instruments.³⁶ “It’s a dangerous practice that borders on fraud,” said Eshoo.³⁷ The proposed Eshoo-Upton legislation would require pre-market approval measuring safety and effectiveness for any medical device intended for reuse. It would also require hospitals to obtain a patient’s informed consent before any recycled item is used in the patient’s care. The legislation would further require hospitals and reprocessing companies to monitor and report any injuries or infections that occur as a result of reusing medical devices.³⁸ Hearings on the bill were conducted by the House of Representatives Subcommittee on Oversight and Investigations in February of this year.

Further Views

Many ethics commentators agree with these and other legislators’ reasoning in support of a ban on or stricter regulation of medical device reuse. One skeptic of medical device reuse, Dr. John H. Fielder, testified before the House Subcom-

³⁴The \$1 million is earmarked for the fiscal year 2000 agriculture spending bill. See Cheryl A. McMullen, “FDA Readies Regulations for Medical Device Reuse,” *Crain’s Cleveland Business* (September 13, 1999) at 18.

³⁵Westphal, *supra* note 13.

³⁶H.R. 3148, entitled Reprocessed Single Use Medical Device Patient Safety Act of 1999).

³⁷Anna Eshoo, “Eshoo and Upton Intro Bill to Stop Reuse of Disposable,” *Congressional Press Release* (October 27, 1999).

³⁸*Id.*

mittee in February, saying: “The patient is the ethical center of health care. All who participate in patient care, directly or indirectly, are ethically obligated to provide adequate and appropriate care to patients and to safeguard their right to make informed health care decisions.”³⁹ Dr. Fielder, in his testimony, noted that studies of reprocessed single-use devices by FDA and others have shown that some devices have debris left in them and are contaminated with fungi, bacteria, or viruses. Reprocessed devices, therefore, can transmit diseases or may fail and injure patients.⁴⁰ He further noted that although there are only a few reports in the literature of patients being harmed by failure of these devices, it is likely that device failures are underreported, and also, that physicians may not always recognize problems caused by reprocessing.⁴¹ Dr. Fielder concluded his testimony by stating that it is “ethically unacceptable” to put people “at risk” without their informed consent.⁴² Dr. Fielder expressed skepticism of the health care savings that hospitals claim would be passed on to patients as a result of SUD reuse, for several reasons. First, it is not guaranteed that any savings would directly affect the patients taking the risk, since savings may well be applied to other hospital service areas. Also, he argued, if these are patients’ benefits, no matter how remote, patients should have the right to decide where they should be spent.⁴³

According to another troubled physician who testified before the House Subcom-

³⁹“Testimony, February 10, 2000, Dr. John H. Fielder, Professor, Philosophy, Ethics Consultant, House Commerce Oversight and Investigations, Reuse of Medical Devices,” *Federal Document Clearing House Congressional Testimony* (February 10, 2000) [hereinafter Fielder statement].

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

mittee, the most significant problem FDA and the government faces involves the reuse of “medical devices that were designed, manufactured, tested, packaged, and labeled for the sole purpose of a single use in a single patient.”⁴⁴ Says he, “These are devices for which the very approval from the FDA is contingent upon information submitted, including the fact that these devices are to be disposed of after a single use.”⁴⁵ This physician, Dr. Grossman, a gastroenterologist in Miami who is also a consultant to a device manufacturers’ group, also argued that single-use devices have a number of common design features that make cleaning or reprocessing difficult or impossible: they tend to be very small and intricate; they typically have complex wiring systems, such as diagnostic wiring that carries an electronic signal for measurement; and because many of these devices are used for the purpose of removing pieces of tissue or altering tissue during a procedure, they typically have sharp points and harp edges, which preclude access to its “nooks and crannies,” encouraging human debris to get caught in tightly woven wires or sharp points.⁴⁶

FDA requires manufacturers to conduct additional testing for devices that are intended to be reusable, Grossman argues. They must meet FDA criteria to validate that a device can be cleaned and resterilized multiple times. Data supporting reuse must be submitted to the FDA through the premarket notification process, whereas FDA is not enforcing these same regulations against reproducers of used single use devices.

Opponents of SUD reprocessing state that public awareness is as yet insufficient

⁴⁴Grossman statement, *supra* note 14.

⁴⁵*Id.*

⁴⁶*Id.*

on this issue. Dr. Grossman, in his February testimony, pointed to a study organized in October 1997 called “The Medical Device Reuse Awareness Study,” conducted for Halsted Communications, that supposedly illustrates public response as people become aware of medical device reuse.⁴⁷ In response to the question posed to 501 participants from Los Angeles, New York, Chicago, and Atlanta, “How would you feel if a device that by law was designed to be used once, was reused on you or on someone you love?,” people responded as follows: 84% stated that they would be angry; 76% would demand an explanation; 69% would be frightened; and 59% would ask for a guarantee that the person that the device was used on before was healthy.⁴⁸ Also, recently in Japan, a clinic initiated a policy in which patients were told that there were two kinds of accessories they could use in a procedure: single-use or reprocessed. If they chose the single-use device, however, they would have to pay an out-of-pocket premium. Everyone chose to pay the premium.⁴⁹ According to Dr. Grossman and other patient advocates, this evidence clearly indicates the strong patient view against any reuse of medical devices in the health care field.

The Hospital Perspective: Efficient Patient Care and Business Necessity.

As noted above, the reprocessing of certain medical devices labeled for single-use has taken place for over two decades. The American Hospital Association (AHA) has called reprocessing “a safe and standard medical practice” that hos-

⁴⁷ *Id.*

⁴⁸ *Id.* 19% of the respondents from Los Angeles also stated that they would sue if they found out what happened.

⁴⁹ *Id.*

pitals have used “for years with excellent success.”⁵⁰ The American College of Cardiology has also written to Congress that “there are cardiovascular specialists who have been using reprocessed catheters in their labs for more than 20 years and cannot cite a single instance where a reprocessed catheter has broken or caused infection.”⁵¹ And the Mayo Clinic has stated that “for more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection.”⁵²

Hospitals, according to one reprocessor, originally began to reprocess for two reasons: First, certain devices initially labeled “reusable” were switched to “single-use” without any structural change in the device. Second, doctors and nurses recognized the inherent waste in discarding certain devices after one use.⁵³ According to one medical device reprocessor, hospitals nowadays are also fully aware that the “single-use” label on a medical device does not necessarily mean that it should be discarded after one use. According to the AHA, “In our view, the real issue is not whether reuse is appropriate, but whether the single-use label is a complete and accurate representation of the device.”⁵⁴ For many hospitals, the single-use label is not an accurate representation.

The American Hospital Association has supported reprocessing and is in favor

⁵⁰“Testimony, February 10, 2000, Mr. Vern Feltner, President, Alliance Medical Corporation, House Commerce Oversight and Investigations, Reuse of Medical Devices,” *Federal Document Clearing House Congressional Testimony* (February 10, 2000) [hereinafter Feltner statement].

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

of appropriate FDA regulation of the practice, rather than an outright ban.⁵⁵ Other spokesmen for hospitals and for companies that reprocess medical devices say that there is no evidence that patients are subjected to any risk from the practice of reprocessing.⁵⁶ These spokesmen believe that state measures such as the one that Senator Bromwell has proposed for Maryland are “an unnecessary overreaction” to national news reports such as those of recycled heart catheters breaking off after being inserted in patients.⁵⁷

The International Association of Healthcare Central Service Material Management has also commented in favor of appropriate FDA regulation, rather than a ban on SUD reprocessing. The association, which includes 8,500 health care professionals responsible for the decontamination, sterilization and organization of medical devices, considers the reprocessing of single-use devices to be a serious patient safety issue. “Our position has been that we don’t recommend reprocessing in health care facilities. If a facility must reprocess to reduce expenses, we recommend they go to a third-party reprocessor that is registered with FDA, who meets the criteria of the [facility’s] health care reuse committee,” association spokeswoman Anne Cofiell has said.⁵⁸

According to FDA medical device chief Dr. David Feigal, even unopened, brand-new, never-before-used heart catheters can break the first time they are used. Also, many medical devices are made to be used over and over — yet they, too, commonly cause infections whenever hospitals do not properly resterilize

⁵⁵McMullen, *supra* note 29.

⁵⁶Wheeler, *supra* note 14.

⁵⁷*Id.*

⁵⁸Cheryl A. McMullen, “FDA debates device reuse,” *Waste News* (December 20, 1999) at 4.

them.⁵⁹ The American Society for Gastrointestinal Endoscopy, a physicians group, has stated: “There is an extensive body of research demonstrating that many devices labeled as ‘single use’ can be reused after proper cleaning and restoration, with no risk to patients.... The only beneficiary of such disposal is the manufacturer of the items.”⁶⁰ Other doctors’ groups, including the American College of Cardiology, have expressed similar support for reprocessing. Furthermore, a physician with the Centers for Disease Control and Prevention recently stated that he “would be just absolutely amazed if [reprocessing] is a major health problem and [the leading hospitals] have failed to realize it.”⁶¹ Four recent clinical studies, all published in peer-reviewed scientific medical journals, have evaluated the safety of reusing heart catheters for certain electrophysiology studies. All of these studies found no evidence that the sterility of reprocessed catheters is a concern or that the incidence of infection is increased.⁶² One study published in the medical journal *Pacing and Clinical Electrophysiology* in 1988, concluded that the catheters were sufficiently durable to be reused well in excess of five times, and that one-time use of such catheters appeared to be a medically unnecessary and expensive policy to adopt.⁶³

Economic Arguments

In recent years, the economic issues of patient care have heightened con-

⁵⁹ “Hospital Recycling Scrutinized,” *Dayton Daily News* (February 11, 2000) at 15A.

⁶⁰ Pam Furman, “These devices are safe,” *USA Today* (November 29, 1999) at 28A.

⁶¹ *Id.*

⁶² “Prepared Statement of Bruce Lindsay, M.D., F.A.C.C., Associate Professor of Medicine, Director, Clinical EP Laboratory, Washington University School of Medicine, St. Louis, Missouri, On Behalf of the American College of Cardiology North American Society of Pacing and Electrophysiology, Before the House Commerce Committee Oversight and Investigations Subcommittee,” *Federal News Service* (February 10, 2000) [hereinafter Lindsay statement].

⁶³ *Id.*

cerns among health care providers and others. Some providers may believe that if disposable medical devices save money, reusing disposable devices will save even more money. Because single-use medical devices can be so expensive,⁶⁴ the cost-effectiveness of reuse might seem obvious.⁶⁵

Richard P. Kidwell, managing attorney for claims and litigation for the Johns Hopkins Health System, asserts that all device reuse is subject to strict internal review for safety.⁶⁶ Hopkins Health System reuses certain catheters in its cardiovascular diagnostic laboratory, as well as laser tips in its Wilmer Eye Institute. Recycling such devices saves about \$2,000 per procedure, Kidwell estimates, which Hopkins passes on to patients and their insurance companies.⁶⁷

Business arguments for the reuse of single-use medical devices center around the need for backup supply systems in the face of device delivery problems; reduced inventory costs and space; and reduced biohazard waste disposal costs. Critics of SUD reuse note that related costs for reprocessing, quality management, liability insurance, and possible lawsuits⁶⁸ make the cost savings of reuse uncertain, however.

But Dr. Bruce Lindsay, a cardiologist and member of both the American College of Cardiology (ACC) and the North American Society of Pacing and Electro-

⁶⁴For example, cardiac catheters, exclusive of sophisticated angioplasty devices, cost \$15 to \$80 each. See M.H. Radany et al., "Is It Safe to Reuse Disposables?", 87 *Am. J. Nursing* 36 (1987).

⁶⁵*Id.* at 35-38; see also "Cardiac Catheter Reuse Targeted by FDA," *F-D-C Rep.* ("The Gray Sheet"), July 7, 1997, at I&W2.

⁶⁶Wheeler, *supra* note 14.

⁶⁷*Id.*

⁶⁸A survey of 501 consumers, conducted for Halsted Communications by Wilson & Associates, found that 19% of respondents stated that they would sue if they discovered that disposable medical devices had been reused in their medical treatment without their informed consent. "Disposable Device Reuse is Opposed by Most Consumers," *F-D-C Rep.* ("The Gray Sheet"), Dec. 22, 1997, at I&W12.

physiology (NASPE), has come out in favor of the economic benefits of medical device reuse. Dr. Lindsay directs the cardiac electrophysiology laboratory at Washington University in St. Louis, where more than 1,500 diagnostic and therapeutic procedures are performed each year. In his 15 years of experience in the field of clinical electrophysiology (EP), Dr. Lindsay has stated that he has never encountered a complication related to the reuse of an EP catheter.⁶⁹ Dr. Lindsay has further noted that the cost of catheters used to perform electrophysiology studies may range from \$100 to as much as \$3,000. Dr. Lindsay also testified before the House Subcommittee in February, and stated then that experience over the past 30 years has indicated that catheters are quite durable and can be sterilized for reuse, as has been the practice for many surgical instruments.⁷⁰

Physicians' motive to reuse EP catheters has arisen from their experience that the catheters are durable and can be safely used for several procedures without posing an increased risk to the patient. As such, says Dr. Lindsay, it would be a waste to discard the catheters after a single use.⁷¹ The cost savings realized by hospitals that reuse catheters, however, can be substantial, depending on the volume of procedures and whether catheters are reprocessed internally or through a commercial reprocessing company. According to Dr. Lindsay, it is possible for hospitals to reduce their catheter costs by about 35% through reuse; and at large medical centers these measures may lead to cost savings in

⁶⁹Lindsay statement, *supra* note 62.

⁷⁰*Id.*

⁷¹*Id.*

the range of \$250,000 to \$400,000.⁷²

Since, according to Dr. Lindsay, cardiovascular specialists have been safely using reprocessed EP catheters to treat their patients for more than 20 years, he urged that the practice has been proven safe, effective, and cost efficient. Lindsay stated that Congressional legislation to ban the practice, such as those introduced by Senator Richard Durbin⁷³ and Representative Anna Eshoo⁷⁴ is unwarranted, and that Congress should “defer to the FDA as it perfects a regulatory strategy for the reuse of medical devices that is based on science and emphasizes public safety as the first priority.”⁷⁵

Some physicians, like Dr. James T. Frakes, a gastroenterologist in Rockford, Illinois, say they do not reuse devices because of liability concerns.⁷⁶ But Dr. Frakes also says that such caution comes at a cost. “We cannot afford to use some single-use accessories in our unit,” he said. Indeed, according to Dr. David E. Haines of the University of Virginia Health System, where electrocardiologists routinely reuse devices that can cost \$1,000 or more per patient (but far less if they are reused), if patients began to insist that the hospital use brand-new devices and equipment, “fresh out of the package,” for every procedure, “we would probably decline to take their cases and refer them elsewhere.”⁷⁷ This result would surely make patient consumers suffer as well, and would this cost be worth the seeming benefit of no more medical device reuse?

⁷²*Id.*

⁷³S. 1542.

⁷⁴H.R. 3148.

⁷⁵Lindsay statement, *supra* note 62.

⁷⁶Gina Kolata, “‘Single Use’ Medical Devices Are Often Used Several Times,” *The New York Times* (November 10, 1999) at A1.

⁷⁷*Id.*

Informed Consent

Regarding the issue of informed consent, such as that raised in Senator Bromwell's proposed Maryland bill, Dr. C. Griffin Trotter of the Center for Health Care at St. Louis University testified before the House Subcommittee in February that "if standards for reprocessing medical devices are sufficiently rigorous to ensure that these devices may be used safely, then there is no moral requirement for informed consent."⁷⁸ He noted before the House that the likely risks pertaining to the use of a reprocessed single-use medical device vary, depending on the nature of the device, the previous use of the device, the reprocessing method and the proposed manner in which the device will be reused. These variations make it difficult to articulate a uniform requirement for informed consent.⁷⁹

Dr. Trotter noted that if it is determined that the risks of using reprocessed medical devices are minimal, then the process of trying to disclose these risks to patients could actually hinder the integrity of informed consent by promoting irrational concerns (thus constraining understanding and voluntariness). This would occur because of two pitfalls. First, patients generally do not reason statistically.⁸⁰ Also, patients often maintain un-warranted superstitions about the hazards of contact with others' bodies, similar to how concern about the transmission of AIDS is sometimes overwrought.⁸¹

Dr. Trotter suspects that "it will not be possible to articulate and legislate

⁷⁸ "Prepared Statement of Dr. C. Griffin Trotter, Center for Health Care, Saint Louis University, Before the House Commerce Committee Oversight and Investigations Subcommittee, Subject - Ethical Issues in the Reuse of Single-Use Medical Devices," *Federal News Service* (February 10, 2000) [hereinafter Trotter statement].

⁷⁹ *Id.*

⁸⁰ For example, even when a risk is statistically very remote, most patients will assume that if it is mentioned, then it is a clinically significant risk. See Trotter statement, *supra* note 78.

⁸¹ *Id.*

a uniform standard for obtaining informed consent for the use of reprocessed SUDs that is more effective or useful than general legal standards that already pertain in clinical medicine.”⁸² A more promising avenue, he suggests, would be to rely on the enforcement of effective safety regulations, which would render informed consent into “a moot issue.”⁸³ Dr. Trotter’s opinions are representative of the views of many doctors on the issue of informed consent and how it relates to medical device reuse, a practice which a majority of physicians believe should continue to be allowed in hospitals without significant restriction.

The OEM Perspective: Mixed Motives?

Original manufacturers of medical devices have continually maintained that hospitals that reuse medical devices are putting patients at grave risk to save money. “The real issue is patient safety,” said Josephine Torrente, president of the Association of Disposable Device Manufacturers. “Until you prove otherwise, these devices are safe and effective for one use. After that, they’re garbage.”⁸⁴

Robert O’Holla, Vice President of Regulatory Affairs for the Medical Devices & Diagnostics Group at Johnson & Johnson, also testified before the House Subcommittee on Oversight and Investigations in February. As Chairman of the Association of Disposable Device Manufacturers, a trade association of single-use medical device manufacturers, he claimed that it was “unacceptable to clean and reuse a delicate, complex medical device that was designed for use in a sin-

⁸² *Id.*

⁸³ *Id.*

⁸⁴ Fred Charatan, “Controversy erupts over reuse of ‘single use’ medical devices,” *The Western Journal of Medicine*, Vol. 172, No. 1 (January 1, 2000) at 58.

gle patient and approved by FDA for only one use.”⁸⁵ O’Holla also expressed his concern regarding the “apparent disinterest” on the part of FDA to the health and safety of patients.⁸⁶ O’Holla called for the FDA to apply all of the provisions of the federal Food, Drug and Cosmetic Act (FDCA or FDC Act) to reprocessed devices. According to him, “No evidence of harm is needed before FDA can and should apply the law. The FDC Act and its implementing regulations establish a presumption that all medical devices are unsafe, and require that the safety and effectiveness of new or substantially modified devices be affirmatively demonstrated prior to their introduction into interstate commerce.”⁸⁷ O’Holla argued that claiming that a single use device may be reused causes the device to be treated as a new device under FDA’s regulatory scheme. O’Holla, in his testimony, cited seven studies of reprocessed biopsy forceps, which indicated that a lack of sterility assurance was reported in over 45% of the samples tested.⁸⁸ Additionally, approximately 75% of the overall 900 samples of reprocessed devices in the studies failed, either due to the presence of blood and/or proteinacious matter, bacterial contamination, non-functionality, or defective packaging.⁸⁹ O’Holla claimed that the studies also found devices with mismatched parts, a scalpel blade designed to be blunt that was, instead, sharpened, a surgical stapler contaminated by a large piece of proteinacious matter, and devices lacking warnings about latex content.⁹⁰

⁸⁵O’Holla statement, *supra* note 3.

⁸⁶*Id.*

⁸⁷*Id.*

⁸⁸*Id.*

⁸⁹*Id.* See also Deborah Circelli, “Medical Recycling: Vanguard Medical Concepts Inc. is part of a growing industry that reprocesses single-use medical equipment and sells it to hospitals,” *The Ledger* (December 12, 1999) at E1.

⁹⁰O’Holla statement, *supra* note 3.

O'Holla and other OEM manufacturers have particularly decried FDA's lack of a premarket approval scheme for reprocessed SUDs. O'Holla cited the Medical Device Amendments of 1976 (MDA), which Congress enacted "for the purpose of implementing pre-market review of devices because Congress was concerned that post-marketing regulation of medical devices was inadequate to protect the public health... there is no justification for a patient to receive less protection from FDA merely because the device used for the patient's treatment is a reprocessed single use device rather than an FDA-cleared reusable device."⁹¹ O'Holla further argued that FDA is violating its Congressional mandate by, in effect, creating a *de facto* exemption from the premarket review requirements for most reprocessed SUDs. "FDA is effecting a double standard that lowers the burden for reprocessors as compared to OEMs. The protection of U.S. patients requires that FDA regulate all manufacturers in the same manner, regardless of whether those manufacturers are deemed OEMs or reprocessors."⁹² O'Holla concluded his testimony by calling for FDA quickly to establish timelines for enforcement of the 510(k) and PMA requirements on all reprocessed SUDs.

Many other medical device manufacturers have complained that they are required to demonstrate to FDA that their products are safe and effective for their intended use before they market them to the public. They argue that reprocessing companies that take their single-use devices and attempt to clean and sterilize them for further use on different patients are not required to prove scientifically that the devices are still safe and effective, and that this constitutes

⁹¹ *Id.*

⁹² *Id.*

inequitable regulatory treatment with regard to OEMs. Some manufacturers believe that by speaking out against medical device reprocessing, they are only asking that the FDA “safeguard patients by closing this regulatory gap.”⁹³ OEMs have further argued that they should not be responsible for providing the data to the FDA on the safety of reusing SUDs,. Those who have the data, they say — “the hospitals and companies that conduct and perpetuate this practice” — should provide the necessary statistics.⁹⁴ However, these entities, they claim, “are resisting the efforts of the FDA and Congress to collect and analyze the data,” through tactics such as “cast[ing] aspersions on the motives of the original manufacturers of the devices in question.”⁹⁵ In response to hospital administrators and device reprocessors who claim that OEMs have only come out against device reprocessing for their own economic motives, one member of the medical device community wrote:

Instead of trying to drive companies that “reprocess” used disposable medical devices out of business, we in the medical device community are trying to ensure that hospitals and companies that reprocess our single-use devices are held to the same regulatory standards as we are. We’re also trying to ensure that patients aren’t injured or infected by the improper use of our products.⁹⁶

To be sure, OEMs have strongly expressed their concern for patient safety and a belief that medical device reprocessing ought to be regulated in the same manner as original device manufacturing. Now we turn to the last stakeholder perspective in this debate, that of the medical device reprocessor.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ “Medical device reuse needs tough scrutiny,” *Chicago Sun-Times* (February 25, 2000) at 36 (Letter to the Editor).

The Reprocessor Perspective: Providing a Service to the Medical Community.

The fast-growing medical device reprocessing industry has maintained that SUD reprocessing and reuse is a safe and effective practice, and that it enables hospitals and other health care providers to contain what might otherwise be spiraling health care costs. Reprocessors have argued that OEMs are so concerned with the reprocessing issue simply because they wish to maximize their own revenues. “The battle is over economics, not safety,” contends one reprocessing industry lobbyist who opposes Bromwell’s Maryland measure.⁹⁷ In an attempt to boost sales, goes the argument, manufacturers arbitrarily label many medical devices for one-time use, even though they had been routinely reused in the past.

Medical administrators and reprocessors argue that the “single-use” designation is a choice made by manufacturers, and is not an FDA requirement.⁹⁸ The Washington-based Association of Medical Device Reprocessors (AMDR) believes that for many devices, the single-use designation is a marketing decision, not a safety decision.⁹⁹ According to the AMDR, “the math is easy — the more devices that are reprocessed, the fewer brand-new devices are purchased, and that much less money is made by manufacturers.”¹⁰⁰

AMDR has presented evidence before the House that manufacturers often designate devices as single-use for economic reasons, rather than out of a concern

⁹⁷Wheeler, *supra* note 14.

⁹⁸Lindsay statement, *supra* note 62.

⁹⁹Feltner statement, *supra* note 50.

¹⁰⁰*Id.*

for patient safety. Moreover, a December 11, 1998 episode of NBC’s “Dateline” exposed Johnson & Johnson’s practice of labeling as “single-use” contact lenses that were virtually identical to the lenses that the company had been marketing as reusable.¹⁰¹ When asked why it had designated the lenses as single-use, Johnson & Johnson stated: “If we had changed the label and marketed for general use, then we couldn’t advertise and create this single-use, daily disposable category. We made that decision because we felt it was a good business decision to do it that way.”¹⁰² Another example involves a letter written by USCI Cardiology & Radiology Products (USCI) to a hospital explaining that, although USCI had decided to change the label on a particular device from reusable to single-use, it had made no structural changes to the device. Specifically, USCI stated: “Our manufacturing processes of Woven Dacron Intracardiac Electrodes have not changed. These electrodes are made with the same materials and in the same manner they have been in the past.”¹⁰³ In light of this evidence, manufacturers’ protestations that the single-use designation on a device is never arbitrary, and that “economics must be subordinate to this concern for proper health” ring hollow for many medical device reprocessors.¹⁰⁴

Charles Masek, president of Vanguard Medical Concepts, has said that his company has safely reprocessed more than 2.5 million devices — ranging from coronary angioplasty balloon catheters and orthopedic blades, burrs, and bits, to deep vein thrombosis sleeves and laparoscopic instruments.¹⁰⁵ Vanguard is a

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Charatan, *supra* note 84.

founding member of AMDR. Mark Salomon, senior vice president of corporate development for Vanguard, has stated that current rising health care costs have caused an even greater need for reprocessing today. Hospitals can save about half the cost of a new device by reprocessing.¹⁰⁶ In addition, the reprocessing industry promotes competition with the OEMs. Salomon said that three years ago, single-use GI biopsy forceps sold for \$60 each, but manufacturers lowered the price to \$30 because of competition from reproducers. Vanguard reprocesses the equipment for \$15 each. Also, angioplasty balloon catheters sold for about \$800 three years ago, but now the price has dropped to \$350. Vanguard reprocesses them for \$175.¹⁰⁷ Vanguard currently reprocesses 13 different types of devices, which Masek said is a narrow spectrum of the hundreds of thousands of medical devices in the health care market.¹⁰⁸

Vern Feltner, President of Alliance Medical Corporation, testified before the House Subcommittee in February 2000, on behalf of AMDR. In his testimony, Feltner claimed that the AMDR did not seek exemption from regulation and oversight.¹⁰⁹ To the contrary, Feltner stated that AMDR and the reprocessing industry could only survive in a “clear, rational regulatory scheme.”¹¹⁰ Feltner cautioned, however, that any regulatory scheme ought to be “based on demonstrated public safety risks and not on hypothetical risks designed to provoke public alarm.”¹¹¹

¹⁰⁶Circelli, *supra* note 89.

¹⁰⁷*Id.*

¹⁰⁸*Id.*

¹⁰⁹*Id.*

¹¹⁰*Id.*

¹¹¹*Id.*

Feltner also testified that hospitals do not reach the decision to reprocess lightly. Rather, they rely on committees made up of physicians, nurses, sterile processing professionals, infection control specialists, risk managers, and hospital lawyers to determine whether a specific device can and should be reprocessed. At each AMDR company, the specific devices are carefully scrutinized in order to determine whether they can safely and effectively be reprocessed.¹¹²

Also, in response to manufacturer complaints that third-party reprocessing is an “unregulated” industry, Feltner points to the regulations that third-party reproprocessors are required to comply with under FDCA, most significantly the Quality System Regulation requirements.¹¹³ Under these requirements, reproprocessors must control and monitor production processes to ensure that a device conforms to its specifications, validate with high degree of assurance that their reprocessing processes ensure that specified requirements are met, and establish and maintain procedures for reprocessed device acceptance to ensure that each production run, lot, or batch meets acceptance criteria.¹¹⁴ In other words, reproprocessors must document that they have developed comprehensive systems to assure that a reprocessed device is clean, sterile, and able to perform its originally intended clinical function. According to Feltner, AMDR companies functionally test every single reprocessed device before sending it back to a hospital, whereas OEM device manufacturers test only a small sampling of their finished devices.¹¹⁵

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ See 21 CFR Part 820; Food, Drug, and Cosmetic Act (FDCA) §520(f).

¹¹⁵ Feltner statement, *supra* note 50.

Feltner concluded that, when performed properly, third-party reprocessing is safe. Since third-party reprocessors are required to comply with “a host of FDA requirements,” hospitals that take advantage of the benefits of third-party reprocessing “can maintain the highest quality patient care, while also achieving significant cost savings.”¹¹⁶

FDA Regulation of Reuse of Single-Use Devices.

Establishments that engage in manufacturing activities, *including* the reprocessing of single use devices for reuse, may be subject to all requirements of the Federal Food, Drug, and Cosmetic Act (FDCA), including: registration and listing,¹¹⁷ premarket notification and approval (PMA) requirements,¹¹⁸ submission of adverse event reports under the Medical Device Reporting (MDR) regulation,¹¹⁹ manufacturing requirements under the Quality Systems (QS) regulation,¹²⁰ and labeling requirements.¹²¹

FDA has recognized generally that user facilities that reprocess medical devices for reuse are “device manufacturers” within the meaning of the FDCA.¹²² In addition, the Medical Device Amendments of 1976¹²³ and the Safe Medical Devices Act of 1990¹²⁴ have provided FDA with broad jurisdiction over device manufacturing.

Thus far, however, the FDA has not regulated OEMs, third-party reproces-

¹¹⁶*Id.*

¹¹⁷21 CFR Part 807; FDCA §510.

¹¹⁸21 CFR Parts 807 and 814; FDCA §§510, 513, 515.

¹¹⁹21 CFR Part 803; FDCA §519.

¹²⁰21 CFR Part 820; FDCA §520(f).

¹²¹21 CFR Part 801; FDCA §502.

¹²²*See* 61 Fed. Reg. 52,602, 52,610 (Oct. 7, 1996).

¹²³Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 15 U.S.C. §55).

¹²⁴Pub. L. No. 101-629, 104 Stat. 4511 (1990) (codified in scattered sections of 21 U.S.C.).

sors, and health care facilities in the same manner with respect to single-use devices.¹²⁵ OEMs have been subject to all the requirements of the FDCA described above.¹²⁶ The agency has also described the current regulatory responsibilities of hospitals that engage in reprocessing in a compliance policy guide.¹²⁷ This policy guide has stated that hospitals that reprocess SUDs assume “full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized, and that device safety, effectiveness, and quality are maintained.”¹²⁸ However, thus far FDA has exercised its enforcement discretion to, in actual practice, exempt third-party reproducers from most premarket and other requirements of the FDCA.

May 1999 FDA and AAMI Conference on Reuse

On May 5-6, 1999, the FDA and the Association for the Advancement of Medical Instrumentation (AAMI) co-sponsored a conference at Crystal City, Virginia on the practice of reprocessing and reusing SUDs. Among conference attendees and participants were representatives of health care facilities, firms that reprocess devices, OEMs, national oversight organizations, state governments, academia, medical ethicists, and standards organizations. This provided the FDA with the opportunity to hear a wide range of views and concerns from individuals and organizations involved in or affected by the practice of medical device reuse.

At this meeting, the FDA received divergent opinions on how reprocessing and

¹²⁵CDRH, “FDA’s Proposed Strategy on Reuse of Single-Use Devices,” *supra* note 9.

¹²⁶Feigal statement, *supra* note 17.

¹²⁷FDA, Compliance Policy Guide 300.500 (November 11, 1977).

¹²⁸*Id.*

reuse of SUDs should be regulated. Some participants believed that reprocessors should be regulated in the same manner as OEMs, and that 510(k)s or Premarket Approval applications (PMAs) demonstrating the safety and effectiveness of the reprocessed device should be required. Others felt that OEMs should be required to provide instructions on how to reprocess their devices unless they can demonstrate that the device cannot be reprocessed.¹²⁹

Participants of the May 1999 conference also identified the need for additional guidance on reprocessing. The suggestions posited included: the promulgation of additional standards to ensure that cleaning, disinfection, and sterilization processes are validated and that reprocessing may be performed properly; a determination of what types of devices can and cannot be reprocessed; a classification scheme establishing critical, semi-critical, and non-critical categories for reprocessed devices; and clearer definitions for the terms “reuse,” “reprocessing,” and “resterilization.”¹³⁰

*November 1999 FDA Proposal*¹³¹

On November 1, 1999, FDA proposed a more clearly-articulated strategy that sought to present the various tasks that the FDA, OEMs, third-party reprocessors, health care facilities, professional health care associations and organizations, the standards development community, and other interested parties could perform in order to address concerns regarding the practice of reprocessing and reusing single-use products in the United States. This proposal was

¹²⁹CDRH, “FDA’s Proposed Strategy on Reuse of Single-Use Devices,” *supra* note 9.

¹³⁰*Id.*

¹³¹All the information found in this section may be found in CDRH, “FDA’s Proposed Strategy on Reuse of Single-Use Devices,” *supra* note 9.

open for a comment period through April of this year, and FDA is currently attempting to pronounce a final and binding regulatory proposal. The November proposal contained eight separate sections elucidating diverse tasks that the agency felt needed to be accomplished. These eight sections will be discussed briefly.

First, FDA proposed to reconsider the agency's current policy on establishments that reprocess SUDs. According to this statement, if FDA ultimately decides to regulate health care facilities that reprocess in the same manner as other reprocessors, such a decision would have a significant impact on the agency's resources, particularly for conducting inspections of these facilities. FDA has indicated that if the agency decided to proceed to regulate health care facilities in the same manner as OEMs, the FDA would consider collaborating with accredited third-party organizations or other federal agencies to inspect these facilities to ensure that reprocessing operations were being performed in accordance with FDA's requirements.

Second, FDA sought to explore the development of a device categorization system based on the level of risk presented by reprocessing and reusing SUDs. From this device categorization system, FDA hoped to formulate an enforcement strategy based on the level of risk. Under this risk-based categorization approach, the agency's application of its authority would depend on the level of risk associated with the reprocessing and reuse of a particular SUD. FDA proposed a three-tiered system of device categorization: "low-risk," "moderate-risk," and "high-risk." Single-use products that are reprocessed because sterility

was breached by means other than patient contact would also be included in this risk categorization scheme.

Factors that FDA considered that could determine a SUD's risk category included: the complexity of procedures associated with reprocessing the device; the actual and potential risk for infection should the reprocessed device be reused; and the quality and extent of published data on reprocessing for the specific device. "High Risk" Reprocessed SUDs would be products the agency believes may pose significant public health risk to patients and users after reprocessing. FDA stated that products in this category should be removed from the market within a short time frame if they have not complied with applicable premarket requirements. For the "high-risk" category, FDA is considering enforcing all of the agency's regulatory requirements, including premarket requirements.

In the category of "Low-Risk" Reprocessed SUDs would be included SUDs that pose "little or no potential public health risk" to patients or users after reprocessing. FDA put forward the expectation that the establishment of inspections for entities that reprocess "low-risk" SUDs to assure compliance with Good Manufacturing Practices (GMP) would be a low priority for the agency. FDA stated an additional plan to exercise enforcement discretion *not* to enforce 510(k) submission requirements, if applicable, for products in this category, provided that the reprocessors have validated reuse procedures or declare conformity to a recognized consensus standard that is applicable to the reprocessed SUD. FDA plans to enforce all other requirements for these products, however, including

registration and listing requirements.

“Moderate-Risk” Reprocessed SUDs would include those products that are not in the “low” or “high” risk categories. FDA would enforce applicable premarket requirements for products in this category to ensure that the reprocessed device remains as safe and effective as a never-used SUD. FDA stated that it planned to utilize its enforcement discretion not to enforce premarket requirements for “moderate-risk” SUDs for a period of two years provided reproprocessors collect, retain, and maintain postmarket data to document the safety, effectiveness, and performance of reprocessed SUDs in this risk category. But FDA would also require reproprocessors of these moderate-risk devices to comply with registration and listing, labeling, corrections and removals, quality systems, and tracking. Finally, with regard to medical device categorization, FDA stated that an SUD’s reuse category under this system might not be a permanent designation. The categorization system would provide flexibility in allowing SUDs to be moved from one category to another, as more data become available on the risks associated with reprocessing and reusing the particular device.

FDA, in its November proposal, also sought to explore how recognized consensus standards can be applied to reprocessing SUDs (for example, to verify and validate cleaning, disinfection and/or sterilization of SUDs). A further goal of FDA is the development of additional consensus standards to address the safety, effectiveness, and performance of reprocessed SUDs. One possibility FDA raised was to allow reproprocessors the option to declare conformity to a recognized standard to ensure that the device remains safe and effective for its intended use. How-

ever, FDA acknowledges that declarations of conformity to consensus standards are voluntary. Also, there are a limited number of device-specific performance standards currently available for SUDs. Therefore, the agency would need to rely heavily on the cooperation and support of stakeholders and would expect interested parties to assume primary responsibility for the development of these standards.

Additional goals mentioned in the FDA November proposal included: examining the need to create working definitions for the terms “single-use device,” “reuse,” “reprocessing,” and “resterilization” such that entities might be aware and informed of their status within the regulatory regime;¹³² soliciting comments on the FDA’s draft list of “Frequently Reprocessed SUDs”;¹³³ and developing a research program on the reuse of SUDs and exploring avenues to publish and disseminate research and other information on reuse. Toward this aim, FDA is considering requesting OEMs to provide information on their labels about risks associated with reuse of SUDs. Existing statutes and regulations already require that devices bear adequate directions for use,¹³⁴ and that the labeling not be false or misleading.¹³⁵ The FDA is also considering requesting OEMs who label their devices “single-use” to provide, as part of the device’s labeling, any information of which they are aware regarding the potential risks associated with reusing their SUDs.

Finally, FDA announced in its November proposal that it would convene an open

¹³² See Appendix A for the FDA’s final proposed definitions for these terms.

¹³³ See Appendix B for the FDA’s draft list of frequently reprocessed SUDs.

¹³⁴ FDCA §502(f).

¹³⁵ FDCA §502(a).

meeting on December 14 to discuss the agency’s proposed strategy. Accordingly, on December 14, 1999, the FDA scheduled an open meeting in Rockville, Maryland to obtain feedback from stakeholders and interested parties on its proposed strategy on reuse of SUDs. 28 public presenters voiced a variety of concerns during the first part of the meeting, and workshops in the afternoon provided attendees with an opportunity to explore particular issues in smaller groups.¹³⁶

February 8, 2000 Draft Guidance Documents

Comments on the November proposal and observations from the December meeting in Rockville, Maryland have resulted in the most recent step that FDA has taken toward formulating a regulatory strategy on the reuse of single-use medical devices. This consists of two draft guidance documents that FDA released on February 8, 2000, that discuss the agency’s prevailing thinking on the issue. The agency also discussed these documents during the U.S. House of Representatives subcommittee hearing on February 10. The guidance documents are not final, said David W. Feigal, head of FDA’s CDRH. But they do incorporate the latest comments on the agency’s proposed strategy.

The new proposed rules would require reproprocessors to “prove they can safely reclean and reuse medical disposable devices — and whether it’s safe to reuse such devices only two or three times, or if ten times is okay.”¹³⁷ In addition,

¹³⁶Feigal statement, *supra* note 17.

¹³⁷“Recycled Medical Devices: FDA Offers More Guidance,” *American Health Line* (February 11, 2000), Politics & Policy Section.

hospitals and resterilizing companies would have to abide by the same FDA safety standards as the devices' manufacturers. Reprocessors wanting to recycle high-risk devices, such as angioplasty balloons, which are hard to clean or sterilize, must seek immediate FDA approval that their methods are "safe and effective."¹³⁸ Low-risk devices could be recycled without prior FDA approval, but must adhere to FDA quality regulations.

The drafts also establish agency priorities for regulating third-party and hospital reprocessors. One draft, titled "The Reprocessing and Reuse of Single Use Devices: Review Prioritization Scheme," describes what factors the FDA would consider in categorizing devices as high-, moderate-, and low-risk.¹³⁹ It also lists commonly reprocessed devices, such as orthodontic braces and angioplasty balloons, and the degree of risk posed by each.¹⁴⁰

The second document, "Enforcement Priorities for Single Use Devices Reprocessed by Third Parties and Hospitals," details current enforcement priorities for the FDA. The risk guidance scheme includes two flowcharts to help the FDA and industry categorize the reprocessing risks.¹⁴¹ One chart addresses elements relating to performance risks of reprocessed devices. The second shows possible failure risk factors.

FDA intends to begin to enforce premarket notification and premarket application requirements within six months of issuance of a final guidance if the reprocessed device is categorized as high-risk; within 12 months if moderate;

¹³⁸ *Id.*

¹³⁹ See Appendices C and D for the flowcharts that FDA has created in order to determine whether a particular medical device should be categorized as high-, moderate-, or low-risk.

¹⁴⁰ See Appendix B.

¹⁴¹ See Appendices C and D.

and within 18 months for a low-risk device, Feigal said.¹⁴² This new FDA proposal was again open for public comment through early April, after which FDA will attempt to finalize their rule.

During the Congressional hearing in February, Rep. Anna Eshoo (D-Calif.) questioned the guidance documents' effectiveness, noting, "FDA says all these devices are subject to regulations, but it won't enforce them unless the device is considered high-risk."¹⁴³ She added that reprocessors using recycled devices deemed moderate- to low-risk will not be required to submit data beforehand. "We can't put patients at risk to save a few dollars," she said.¹⁴⁴

Suggestions and Recommendations for the FDA.

To legislators like Eshoo and others, patient safety is of utmost concern, but health care cost containment is also of extreme importance. In this age of rising health care costs, is reprocessing a technology that offers a solution? Dr. Grossman has posited to FDA and Congress the question: would you want your loved ones who had the misfortune of being ill to be in the care of a doctor or a hospital where you not only needed to worry about the disease that has afflicted them, but also had to worry about the safety of the very device used to try to bring about their wellness?¹⁴⁵

FDA has not yet issued a compliance policy guide that addresses third-party reprocessors of SUDs, although the agency has issued statements in response

¹⁴²Cheryl A. McMullen, "FDA studies instrument reuse," *Waste News* (February 21, 2000) at 3.

¹⁴³"Recycled Medical Devices: FDA Offers More Guidance," *supra* note 137.

¹⁴⁴*Id.*

¹⁴⁵Grossman statement, *supra* note 14.

to specific inquiries. Under current agency policy, third-party reproprocessors are subject to registration, listing, QS, labeling, and MDR reporting requirements. A recent letter from an agency director has also stated that third-party reproprocessors are subject to premarket requirements.¹⁴⁶ The FDA however, has noted that many devices that are commonly reprocessed are exempt, by regulation, from premarket requirements. And over the years, the agency has issued warning letters to third-party reproprocessors for a variety of violations,¹⁴⁷ including: failure to comply with quality systems requirements, including failure to validate sterilization procedures; failure to carry labeling statements that a device has been reprocessed; and failure to bear adequate directions for use.¹⁴⁸ While the agency-promulgated regulations may require third-party reproprocessors who engage in certain manufacturing activities to comply with premarket requirements, the FDA, in its enforcement discretion, has as yet not taken action against third-party reproprocessors on the basis of noncompliance with premarket notification requirements.¹⁴⁹

FDA regulation on this issue is currently stagnant. The agency is continually saying that it needs more clinical data and experience on reuse before it is willing to formulate a clear regulatory stance on SUD reuse; however, the practice has been occurring for over 20 years now, and FDA still maintains that it does not possess enough data. Even if the data were insufficient, FDA has already

¹⁴⁶CDRH, “FDA’s Proposed Strategy on Reuse of Single-Use Devices,” *supra* note 9.

¹⁴⁷*Id.* But see also, Feltner statement, *supra* note 50, noting that many OEM device manufacturers themselves also receive warning letters from FDA.

¹⁴⁸This regulation is prescribed under 21 U.S.C. 352 (f)(1).

¹⁴⁹CDRH, “FDA’s Proposed Strategy on Reuse of Single-Use Devices,” *supra* note 9. See also Feigal statement, *supra* note 17.

been mulling over the issue for some three years now.

The agency has called for long-term clinical studies, the establishment of a clearinghouse for data, dedication of National Institutes of Health (NIH) funds to study reprocessing, and research to be conducted by professional societies with funding provided by OEMs and reprocessors. However, much more needs to be done. FDA is currently accomplishing little by dragging its feet. Patient lives may be at stake, and more resources must be devoted to regulation, even though the limited resources of FDA are immediately apparent.

FDA seems, thus far, to have been characterized by hesitation, indecision, and uncertainty on this matter. Dr. Feigal's perpetual refrain to the press has been that "[d]espite a lack of clear data that suggests that many injuries are occurring due to reprocessing practices, FDA has concluded that the practice of reuse of [SUDs] needs additional attention and controls."¹⁵⁰ However, up until now, FDA has been unwilling or unable to devote the additional attention or controls that may be necessary for this practice. So far, only 8 companies that reprocess disposables for hospitals have registered with the FDA as required by law, according to agency officials. Another nine may be registered under different names, and another five may be in business.¹⁵¹ Also, since 1994, FDA has only inspected six reprocessing companies — or slightly less than a third of those in business.¹⁵²

For many agency officials, FDA is guilty of "inexcusably belated" action. Ac-

¹⁵⁰Cheryl A. McMullen, "FDA studies instrument reuse," *Waste News* (February 21, 2000) at 3.

¹⁵¹"FDA exposes patients to risks of medical recycling," *USA Today* (November 30, 1999) at 18A.

¹⁵²*Id.*

cording to Larry Kessler, Director of the Office of Surveillance and Biometrics at CDRH of the FDA, “The idea of doing something tomorrow doesn’t make any sense... What FDA needs to do is help take the leadership role in creating a shared vision for what [the practice] should look like in five and ten years.”¹⁵³ Plainly, FDA’s responsibilities stretch its resources. Congress needs to give it more money and more authority. But, say some, the reuse of disposable devices “violates both the spirit of the FDA’s charter and the faith of consumers.”¹⁵⁴ The main issues that FDA ought to focus on when trying to formulate a regulatory scheme are as follows. Should hospitals that recycle and third-party reproducers be forced to register with FDA and list the devices they reuse, how they are cleaned, and what problems result? The answer seems to be clearly yes; too many issues of concern are at stake, and if hospitals wish to continue to reprocess in order to cut costs, they ought also to be willing to take on the additional administrative burden of proving to FDA that such practices are safe and effective. Should hospitals also inform patients that they will be treated with reused disposables and offer alternatives, even if alternatives come at a higher cost? The answer to this question seems less clear, since it appears that higher-expense alternatives may have the undesirable side effect of making health care reach prohibitive cost levels for health care consumers. FDA ought to investigate this question very closely, weighing very carefully and attempting to balance the competing concerns of patient safety, informed consent, and hospital and physician discretion.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

Further, one step which FDA has not yet proposed and which would be beneficial to the health care industry as a whole is that OEMs should be required to submit public documents explaining why a device is labeled as single-use. Therefore, possible ulterior economic motives for the “single-use” label might be removed altogether, allowing for an appropriate and proper labeling scheme that only takes patient safety into account. Device makers, hospitals, and repro- cessors should also finance FDA-sponsored research to develop quality and man- ufacturing standards for the riskiest devices, and hospitals and makers should submit data on adverse events in a way that clearly indicates whether reuse was a cause. If FDA takes these additional proactive steps in regulating this growing industry of medical device reuse, a comprehensive regulatory scheme should emerge, one in which hospitals, patients, original device manufacturers, and device reproducers will be able to discern with confidence their various rights and responsibilities.

Appendix A: FDA Proposed Guidance Definitions¹⁵⁵

Single-use device: A single-use device is a device that is intended to be used only on one patient during a single procedure. It is not intended to be reprocessed (cleaned and disinfected/sterilized) and used on another patient. This labeling identifies the device as disposable and does not include instructions for reprocessing. Some single-use devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.

Opened-but-unused: An opened-but unused device is a single-use device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient.

Reuse: The repeated use or multiple use of any medical device including reusable and single-use medical devices, on the same patient or on different patients, with applicable reprocessing (cleaning and disinfection/sterilization) between uses.

Reprocessing: Includes all operations performed to render a contaminated reusable or single-use device patient-ready. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

Resterilization: The repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility level.

¹⁵⁵Definitions obtained from CDRH, “Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,” at <<http://www.fda.gov/cdrh/reuse/1029.html>>.

**Appendix B: List of Frequently Reprocessed Single-use
Devices
and Their Risk Classifications¹⁵⁶**

Medical Specialty Service	Device	Regulation #	Type of Premarket Submission	Risk Category
Cardio-vascular	Angiography catheter	870.1200	510(k)	high
	Blood Pressure Cuff	870.1120	510(k)	low
	Cardiac Ablation Catheter	unclassified	PMA	high
	Cardiac Guidewire	870.1330	510(k)	high
	Compressible Limb Sleeve	870.5800	510(k)	low
	Electrophysiology Recording Catheter	870.1120	510(k)	high
	Intra-aortic Balloon Catheter	870.3535	510(k)	high
	Needle	870.1390	510(k)	high
	Percutaneous Trans-luminal Coronary Angioplasty (PTCA) Catheter	unclassified	PMA	high
	Percutaneous Trans-luminal Angioplasty (PTA) Catheter	unclassified	510(k)	high
	Syringes	870.1650, 870.1670, unclassified	510(k)	high
	Trocar	870.1390	510(k)	moderate
	Breathing Mouth-piece	868.5620	N/A	low
Respiratory	Endotracheal Tubes	unclassified	PMA	high
	Masks	868.5550	N/A	low
	Oral and Nasal Catheters	868.5350	N/A	low
	Respiratory Therapy and Anesthesia Breathing Circuits	868.5240	N/A	moderate
	Tracheobronchial Suction Catheter	868.6810	510(k)	high

¹⁵⁶Chart partially obtained from CDRH, “Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme” at <<http://www.fda.gov/cdrh/reuse/1156.html>>.

Gastro- enterology/ Urology	Biliary Sphincter- tomes	876.4300	510(k)	high
	Biopsy Needles	876.1075	510(k)	high
	Endoscopic Guidewires	876.1500	510(k)	low
	Endoscopic Staplers	876.4400	510(k)	low
	Extraction Balloons/ Baskets	876.1500	510(k)	high
	Non-Electric Biopsy Forceps	876.1075	510(k)	high
	Trocar	876.5090	510(k)	low
	Urethral Catheters	876.5130	510(k)	moderate
Nephrology	Hemodialysis Blood Tubing	876.5820	510(k)	moderate
OB-GYN	Laparoscopic Dissec- tors	884.1720	N/A	low
	Laparoscopic Graspers	884.1720	N/A	high
	Laparoscopic Scissors	884.1720	N/A	high
	Trocar	884.1720	510(k)	low
Orthopedics	Arthroscopy Instru- ments	888.1100	510(k)	low
	Carpal Tunnel Blade	888.4540	N/A	moderate
	Drill Bits	878.4540	N/A	low
	External Fixation De- vice	878.3900, 878.3910	N/A	low
	Flexible Ream- ers/Drills	878.4820, 886.4070	N/A	low
	Saw Blades	878.4820	N/A	low
	Surgical Drills	878.4820	N/A	low
Surgery	Biopsy Forceps	874.4680, 876.1075, 876.4300, 884.4530	510(k)	high
	Biopsy Needles	878.4800	N/A	high
	burr	878.4820	N/A	low
	Electrosurgical Electrodes/ Han- dles/Pencils	876.4300, 878.4800	510(k)	moderate
	Endoscopes	876.1500	510(k)	high
	Endoscopic Blades	876.1500	510(k)	moderate
	Endoscopic Guidewires	876.1500	510(k)	low

	Endoscopic Staplers	888.4540	N/A	moderate
	Fascia Holders	878.4800	N/A	moderate
	Laproscope	876.1500, 884.1720	510(k)	low
	Laser Fiber Delivery Systems	874.4496, 874.4500, 874.4770, 878.4810, 884.4550, 886.4390, 886.4690	510(k)	low
	Scissor Tips, Removable Inserts	874.4420, 878.4800, 884.4520, 888.4540	N/A	moderate
	Surgical Cutting Accessory	874.4420, 878.4800	N/A	moderate
	Trocar	870.1390, 874.4420, 876.1500, 876.5090	510(k)	moderate
Plastic Surgery	Stapler	878.4800, 882.4190	N/A	moderate
Laboratory	Glucometer Lancets	878.4800	N/A	low
Ophthalmic	Keratome Blade	886.4370	510(k)	high
	OR Drapes	878.4370	510(k)	moderate
	Phacoemulsification Needle	886.4670	510(k)	high
Infection Control	OR Gowns	878.4040	510(k)	low
	Sharps Containers	880.5570	510(k)	low
	Syringes, Piston	880.5860	510(k)	high
General Hospital	Infusion Pump, Implanted	unclassified	PMA	high
	Syringe, Irrigating	880.6960	N/A	low
Dental	Braces, Plastic	872.5470	510(k)	high
	Braces, Metal	872.5410	N/A	high
	Burr	872.3240	N/A	moderate

Appendix C¹⁵⁷

¹⁵⁷ *Id.*

Appendix D¹⁵⁸

¹⁵⁸ *Id.*